EXHIBIT 101

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

EXCESSIVE MEDICARE PAYMENTS FOR PRESCRIPTION DRUGS

JUNE GIBBS BROWN
Inspector General

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OFFICE OF INSPECTOR GENERAL

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EXECUTIVE SUMMARY

PURPOSE

To compare Medicare allowances for prescription drugs with drug acquisition prices currently available to the physician and supplier communities.

BACKGROUND

Medicare allowances for prescription drugs increased 25 percent from $1.8 billion in 1995 to $2.3 billion in 1996. However, the number of services allowed increased only 9 percent between the 2 years.

Medicare does not pay for over-the-counter or many prescription drugs that are self-administered. However, the program does pay for certain categories of drugs used by Medicare beneficiaries.

On January 1, 1998, Medicare Part B will begin to reimburse covered drugs at 95 percent of the average wholesale price. Currently, Medicare carriers may determine the amounts that Medicare will pay for these drugs based on either the lower of the Estimated Acquisition Cost (EAC) or the national Average Wholesale Price (AWP). The EAC is determined based on surveys of the actual invoice prices paid for the drug. The AWP is reported in *The Red Book* and other pricing publications and databases used by the pharmaceutical industry. Historically, it has been the AWP that carriers have used to develop Medicare reimbursement for prescription drugs.

To determine if average wholesale prices paid by Medicare truly represent wholesale prices available to physicians and prescription drug suppliers, we focused on 22 drug codes representing the largest dollar outlays to the program in 1995. We then compared the Medicare allowances for these drug codes with prices available to the physician and supplier communities.

FINDINGS

Medicare allowances for 22 drugs exceeded actual wholesale prices by $447 million in 1996.

Medicare and its beneficiaries payments for the 22 drugs would have been reduced by an estimated 29 percent ($447 million of $1.5 billion) if actual wholesale prices rather than AWP's were the basis for Medicare reimbursement. Similar savings of $445 million were also identified for 1995. If the savings percentage for just the 22 drugs was applied to Medicare's allowances for all drugs, the program and its beneficiaries would have saved an estimated $667 million in 1996.

For more than one-third of the 22 drugs reviewed, Medicare allowed amounts were more than double the actual wholesale prices available to physicians and suppliers.

Medicare allowed between 2 and 10 times the actual average wholesale prices offered by drug wholesalers and group purchasing organizations for 8 of the 22 drugs reviewed. Medicare allowed at least 20 percent more than the actual average wholesale price for over 80 percent of the 22 drugs. For every one of the 22 drugs reviewed, Medicare allowed amounts were more than the actual average wholesale price in both 1995 and 1996. Not only did Medicare pay more than the actual average wholesale price, the program allowed more than the highest average wholesale price for every drug.

There is no consistency among carriers in establishing and updating Medicare drug reimbursement amounts.

Although Medicare's reimbursement methodology for prescription drugs does not provide for different payment rates based on geographical factors, the allowed amounts for individual drug codes varied among the carriers. Medicare guidelines allow carriers to update prescription drug reimbursement on a quarterly basis. However, not only did some carriers update yearly rather than quarterly but carrier allowed amounts for the same drug code differed within a single quarter.

RECOMMENDATIONS

The findings of this report provide evidence that Medicare and its beneficiaries are making excessive payments for prescription drugs. The published AWPs that are currently being used by Medicare-contracted carriers to determine reimbursement bear little or no resemblance to actual wholesale prices that are available to the physician and supplier communities that bill for these drugs.

We believe the information in this report provides further support for a previous recommendation made by the Office of Inspector General. **We recommended that HCFA reexamine its Medicare drug reimbursement methodologies, with the goal of reducing payments as appropriate.** Beginning in January 1998, Medicare reimbursement for prescription drugs will be 95 percent of average wholesale price. We believe that the 5 percent reduction is not a large enough decrease and that further options to reduce reimbursement should be considered.

We also believe that the variance of Medicare reimbursement for individual drug codes among carriers is inappropriate. The rate at which physicians and suppliers are paid for drugs should not depend on which carrier the providers bill. **We, therefore, recommend that HCFA require all carriers to reimburse a uniform allowed amount for each HCFA Common Procedural Coding System (HCPCS) drug code.** The HCFA could choose to supply all carriers with a list of average wholesale prices that it has determined represent each drug code. The carriers could then use the uniform prices to calculate payment. The HCFA could also designate one single entity to perform all

necessary calculations to determine reimbursement for each drug code on a quarterly basis. All carriers would then use this standard reimbursement amount.

AGENCY COMMENTS

The HCFA concurred with our recommendations. The HCFA's proposal in the President's 1998 budget that would have required physicians to bill Medicare the actual acquisition cost for drugs was not adopted by Congress. However, the agency states that it will continue to pursue this policy in other appropriate ways.

We support HCFA's continued pursuance of reducing drug payments where appropriate. We do not believe that the reimbursement methodology for prescription drugs recently adopted by Congress will curtail the excessive drug payments we've identified in the Medicare program. In this report we've identified Medicare allowances that were 11 to 900 percent greater than drug prices available to the physician and supplier communities.

To address the issue of uniformity among carriers, HCFA has convened a workgroup to develop an electronic file consisting of the average wholesale prices for drugs covered by Medicare. The agency reports it will distribute this file to Medicare contractors for their use in paying drug claims.

TABLE OF CONTENTS

INTRODUCTION

PURPOSE

To compare Medicare allowances for prescription drugs with drug acquisition prices currently available to the physician and supplier communities.

BACKGROUND

Medicare allowances for prescription drugs increased 25 percent from $1.8 billion in 1995 to $2.3 billion in 1996. However, the number of services allowed increased only 9 percent between the two years.

Medicare Coverage and Payment for Prescription Drugs

While Medicare does not pay for over-the-counter or many prescription drugs that are self-administered, it does pay for certain categories of drugs used by Medicare beneficiaries. Under certain circumstances, Medicare Part B covers drugs that are used with durable medical equipment or infusion equipment. Medicare will cover certain drugs used in association with dialysis or organ transplantation. Drugs used for chemotherapy and pain management in cancer treatments are also covered. The program also covers certain types of vaccines such as those for flu and hepatitis B.

Depending on the type of drug, both local carriers and four Durable Medical Equipment Regional Carriers (DMERCs) are responsible for processing claims for drugs covered under Part B of the Medicare program. The carriers are responsible for determining the allowance that Medicare will pay for these drugs.

Carriers base their current allowance rates on the regulations established in 42 Code of Federal Regulation 405.517. According to the regulations, Medicare computes an allowed amount for drugs based on either the lower of the Estimated Acquisition Cost (EAC) or the national Average Wholesale Price (AWP). The allowed amount is the price that Medicare and its beneficiaries pay a drug supplier. The EAC is determined based on surveys of the actual invoice prices paid for the drug. The AWP is determined through *The Red Book* or similar pricing publications and databases used by the pharmaceutical industry. The AWPs are mainly provided to these sources by pharmaceutical manufacturers. If a drug has multiple sources (more than one brand or generic version), the price is based on the lower of the EAC or the median of the national AWP for all generic sources. Historically, carriers have utilized AWP and not estimated acquisition cost to develop Medicare reimbursement for prescription drugs.

Drugs are billed to the Medicare program based on codes developed by the Health Care Financing Administration (HCFA). These codes are developed as part of the HCFA Common Procedure Coding System (HCPCS). The codes define the type of drug and, in most cases, a dosage amount. The codes do not indicate whether a brand

or generic version of the drug was administered; nor do the codes provide information on the manufacturer or distributor of the drug provided.

Change in Medicare Reimbursement for Prescription Drugs

In recent legislation, Congress established reimbursement for prescription drugs at 95 percent of a drug's average wholesale price. This change will be implemented on January 1, 1998.

A different proposal to change the Medicare reimbursement methodology for prescription drugs was included in the President's FY 1998 budget. The proposal provided for the amendment of 42 U.S.C. 1395u(o) to set payment for drugs not otherwise paid on a cost or prospective payment basis. The revision set payment at the lowest of: actual acquisition cost to the provider, AWP, median actual acquisition cost, or an amount otherwise determined under the Code. The actual acquisition cost was defined to include all discounts, rebates, or any other benefit in cash or in kind. This proposal was supported by HCFA but was not the version eventually adopted by Congress.

Related Work by the Office of Inspector General

This report is one of several Office of Inspector General reports concerning Medicare payments for prescription drugs. In 1996, we released a report entitled *Appropriateness of Medicare Prescription Drug Allowances* (OEI-03-96-00420) which compared Medicare drug reimbursement mechanisms with Medicaid payment mechanisms for 17 drugs and found that Medicare could achieve significant savings by adopting reimbursement strategies similar to those used by Medicaid. The OIG has also produced several reports focusing on inhalation drugs paid for by Medicare. In *Medicare Payments for Nebulizer Drugs* (OEI-03-94-00390), we found that Medicaid reimbursed albuterol sulfate and other nebulizer drugs at significantly lower prices than Medicare. In a companion report called *A Comparison of Albuterol Sulfate Prices* (OEI-03-94-00392), we found that many retail and mail-order pharmacies charge customers less for generic albuterol sulfate than Medicare's allowed price. *Suppliers' Acquisition Costs for Albuterol Sulfate* (OEI-03-94-00393) found that Medicare's allowances for albuterol sulfate substantially exceeded suppliers' acquisition costs.

The Office of Inspector General also recently issued a report on acquisition costs of brand name drugs by Medicaid pharmacies. In *Medicaid Pharmacy - Actual Acquisition Costs of Prescription Drug Products for Brand Name Drugs* (A-06-96-00030), the Office of Audit Services estimated that the actual acquisition cost for brand name drugs was 18 percent below AWP.

METHODOLOGY

To determine if average wholesale prices paid by Medicare truly represent wholesale prices available to physicians and prescription drug suppliers, we focused on drug

codes representing the largest dollar outlays to the program in 1995. We then compared the Medicare allowances for these drug codes with prices available to the physician and supplier communities.

We collected from three sources the data needed to compare Medicare allowed amounts to actual wholesale prices. For information on Medicare allowances for prescription drugs, we compiled statistics from HCFA's National Claims History (NCH) File. We then collected Medicare reimbursement rates for specific drugs from contracted carriers. Lastly, we analyzed wholesale prices from drug wholesalers and group purchasing organizations.

Medicare Allowance Data for Prescription Drugs

We decided to review the 30 drug codes with the highest Medicare allowances for 1995. We chose 1995 since the Medicare claims data was 98 percent complete at the commencement of the inspection. To determine the Medicare allowances for prescription drugs in 1995, we compiled a list of HCPCS codes that represent all of the drugs which Medicare reimburses. The drug code list primarily contained HCPCS codes beginning with a J (known as J codes) which represent mainly injectable drugs or drugs used in conjunction with durable medical equipment. Also included in our list of drugs were K codes which usually represent immunosuppressive drugs, Q codes which represent mainly drugs used for End Stage Renal Disease, several A codes that represent drugs used for diagnostic imaging, and immunization or vaccine codes that are represented by a five digit numeric code.

We then retrieved NCH allowance and utilization data using HCFA's Part B Extract and Summary System (BESS). We aggregated the allowances for each code to calculate Medicare's total prescription drug allowance for 1995. We then determined the 30 drug codes with the highest individual allowances for that year.

Using NCH data, we calculated the Medicare allowances for all drugs in 1996. We also determined the 1996 allowances for the 30 drug codes with the highest allowances in 1995. At the time of our inspection, the NCH data for 1996 was 95 percent complete.

Carrier Allowances for Prescription Drugs

We sent requests for carrier drug reimbursement rates to Medicare's 26 fraud information specialists. The fraud information specialists coordinate work among all HCFA contractors in the regions they represent. There are a total of 61 geographical regions that local carriers cover. We received drug allowances from 50 of the 61 areas. We also received responses from two of the four DMERCS.

We requested allowed amounts for prescription drug codes with the highest total allowances in 1995. The allowed amount reflects the dollar reimbursement that Medicare will allow for the specific dosage defined by the HCPCS drug code. We

asked the carriers to provide allowed amounts by quarter for calendar years 1995, 1996, and 1997. However, some carriers provided us with data on a yearly basis and others only for certain quarters.

Some carriers also furnished allowed amounts for both participating and non-participating physicians. Physicians participating in the Medicare program agree to accept Medicare allowed amounts as total reimbursement for their services. Participating physicians receive 5 percent more in Medicare reimbursement for services. In the instances where both participating and non-participating allowed amounts were provided, we used the participating physician allowed amounts. More than three-quarters of physicians across the nation now participate in the Medicare program.

Utilizing the data provided by carriers, we calculated an average Medicare allowed amount for each drug code by year. These allowed amounts were used to compare Medicare reimbursement with drug acquisition costs for physicians and suppliers.

Prescription Drug Costs for Physicians and Suppliers

In order to determine acquisition costs for the top drugs, we reviewed 1995 and 1996 prices offered by wholesale drug companies and group purchasing organizations (GPOs). We obtained pricing lists/catalogs for seven wholesale drug companies and seven group purchasing organizations. Group purchasing organizations provide members with lower cost products by negotiating prices for specific drugs from manufacturers. The member can then purchase drugs at the negotiated price either directly from the manufacturer or a drug wholesaler that agrees to accept the negotiated price. For the GPOs we reviewed, most of the major drug wholesalers accept the GPO contracted price.

The 14 pricing sources we used provided pharmaceutical products mainly to physician practices and specialized or closed pharmacies. Depending on individual State licensing practices, specialized or closed pharmacies normally do not provide retail prescription drug dispensing to walk-in customers. Instead, they often provide prescription drugs for home infusion or inhalation therapy.

After beginning our review of wholesale drug costs, we determined that 2 of the top 30 drugs codes we identified for 1995 could not be used for the inspection. Code J7699 represents not-otherwise-classified inhalation drugs and Code J7190 for Factor VIII (human anti-hemophilic factor) has a dosage requirement that is difficult to determine. Therefore, obtaining wholesale prices for these two codes would not be possible.

For the remaining 28 drug codes identified for our analysis, 17 were used for the treatment of cancer/leukemia, 5 were inhalation drugs, 2 were vaccines, and 2 were used for organ transplantation or valve replacement complications. There was also a drug used for immunodeficiencies and another for severe infections. The majority of

these drugs would most likely be purchased and administered by physicians or other health care practitioners. The inhalation drugs or drugs used for home infusion would most likely be provided by a specialized pharmacy or supplier.

For the 28 drug codes, we collected 1995 and 1996 prices from the 14 drug pricing lists/catalogs. We decided not to present prices for drugs where fewer than two different pricing sources could be identified per year. There were 6 codes that did not meet the two source minimum. These codes were: vaccine codes 90724 and 90732, inhalation codes J7645 and J7660, and codes K0121 and J1245 used for transplants/valve replacements. A list of the HCPCS codes' descriptions and dosages for the final 22 drugs used for our evaluation is provided in Appendix A.

The 22 drug codes represented 10 single-source, 9 multiple-source, and 3 multiple-brand drugs. A single-source drug has only one brand of drug available. A multiple-source drug has both brand and generic forms of the drug available. There were no drug products manufactured in the dosage defined by the HCPCS code for five drugs (J7620, Q0136, J2405, J9181, J9293). We selected all the drugs with higher dosages that met the drug description and applied a conversion factor to achieve prices for the HCPCS-specified dosage. For an additional code (J1561), we found that out of the multitude of prices we could find for the drug only three met the exact dosage requirement. Since the higher dosage products seemed to be the more prevalent way of purchasing this drug, we included them in our analysis.

We searched the 14 price lists for both brand and generic prices during 1995 and 1996. For nine drug codes, we obtained between 5 and 8 separate prices. Eight of the nine were single-source drugs. For another eight codes, we found between 12 and 29 separate prices. We found between 30 and 70 separate prices for the remaining five drug codes.

Calculation of Potential Medicare Savings for Prescription Drugs

To determine the potential savings to Medicare if acquisition costs rather than published AWPs were used for reimbursement, we compared Medicare's allowed amounts to the wholesale prices we collected. To do this, we compiled all the pricing information from the sources reviewed and calculated an average price by year for all 22 codes. We believe that the pricing information supplied by the drug wholesalers and group purchasing organizations provides factual evidence of acquisition costs available to physicians and suppliers.

The average price or average acquisition cost for each drug code was then compared to the average Medicare allowed amount that we calculated from the carrier data. For each drug code, the difference between the average price and the Medicare allowed amount was computed. We then applied this amount to the number of services paid by Medicare for each drug in 1995 and 1996. The resulting dollar amounts were aggregated to determine the total estimated savings to Medicare if acquisition costs rather than AWP had been used to determine reimbursement.

Appendix B provides the average Medicare allowed amounts and actual average wholesale prices computed for the 22 drug codes reviewed. Although we utilized the actual average wholesale price to report savings in the findings section of this report, the appendices also contains the potential savings to Medicare if the lowest and highest wholesale prices found were compared to the Medicare allowed amount.

FINDINGS

MEDICARE ALLOWANCES FOR 22 DRUGS EXCEEDED ACTUAL WHOLESALE PRICES BY $447 MILLION IN 1996.

Medicare carriers now base prescription drug reimbursement on published average wholesales price of drugs. However, physicians and suppliers are often able to purchase drugs for prices that are much lower than the official AWPs provided by manufacturers.

After reviewing wholesale drug catalogs and group purchasing organizations' prices for the 22 drugs, we estimated that $447 million would have been saved by Medicare and its beneficiaries if Medicare had based reimbursement on actual wholesale prices rather than published AWPs in 1996. These wholesale prices are available to physicians, specialized pharmacies, and other suppliers. These wholesale prices represent the actual acquisition costs to physicians and suppliers that bill Medicare for these drugs.

Total allowed charges for the 22 drugs would have been reduced by 29 percent ($447 million of $1.5 billion) if actual wholesale prices rather than AWP were the basis for Medicare reimbursement. The 22 drugs represented 67 percent of the $2.3 billion in total Medicare drug allowances for 1996. If the savings percentage for just the 22 drugs was applied to Medicare's reimbursement for all drugs, the program and its beneficiaries would have saved an estimated $667 million in 1996.

The savings for individual drugs ranged from 13 percent of allowances for three drugs (J9202, Q0136, J9185) to a high of 92 percent for leucovorin calcium (J0640). Almost half of the drugs (10 of 22) had estimated savings greater than 40 percent of allowances. A table provided in Appendix C lists the 1996 allowances and estimated savings for the 22 drugs. The table also lists the percentage of allowance saved for each individual drug if reimbursement had been based on the actual average wholesale prices available for the drug.

Similar savings of $445 million were identified for 1995.

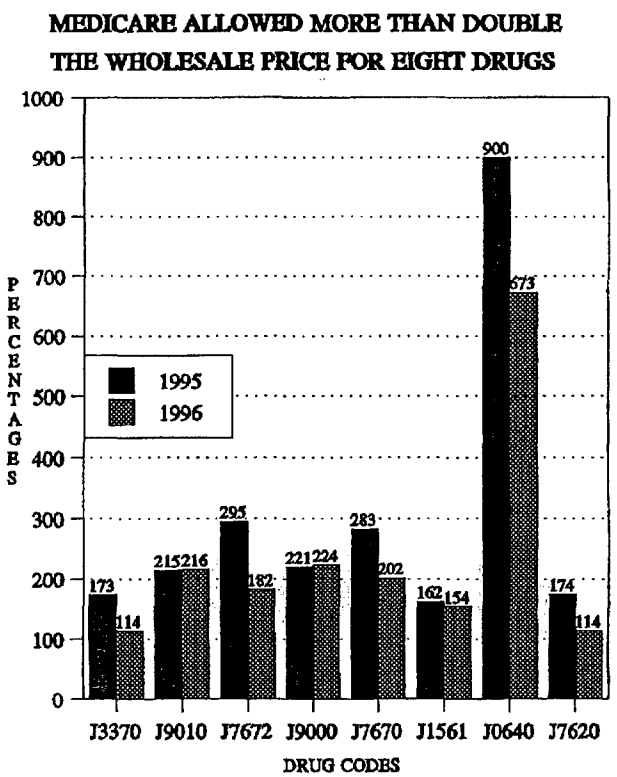
If Medicare had based reimbursement on actual wholesale costs in 1995, the program and its beneficiaries would have saved an estimated 35 percent in payments for the 22 drugs. This would have amounted to savings of $445 million on $1.3 billion in total 1995 program expenditures for these drugs. The $1.3 billion in expenditures for the 22 drugs represented 70 percent of the $1.8 billion in Medicare total drug allowances for 1995.

The percentage of allowance saved for individual drugs ranged from 15 percent for carboplatin (J9405) and fludarabine phosphate (J9185) to 95 percent for leucovorin calcium (J0640). Half of the drugs (11 of 22) had estimated savings greater than 40

percent of their 1995 allowances. Individual drug allowances and savings for 1995 are presented in Appendix C.

FOR MORE THAN ONE-THIRD OF THE 22 DRUGS REVIEWED, MEDICARE ALLOWED AMOUNTS WERE MORE THAN DOUBLE THE ACTUAL AVERAGE WHOLESALE PRICE AVAILABLE TO PHYSICIANS AND SUPPLIERS.

Medicare allowed between 2 and 10 times the actual average wholesale prices offered by drug wholesalers and group purchasing organizations for 8 of the 22 drugs reviewed. For one drug, Medicare allowed 900 percent more than the average price available for the drug in 1995 and 673 percent more in 1996. The chart below provides the percentage of the Medicare allowed amount that is greater than the actual average wholesale price for each of the eight drugs.



Medicare allowances were also significantly higher than acquisition costs for the remaining 14 drugs reviewed. Medicare allowed 60 to 95 percent more than the actual average wholesale price for 3 drugs in 1995 and 2 drugs in 1996. Medicare allowed amounts were higher by 20 to 50 percent for 9 drugs in 1995 and 8 drugs in 1996. Reimbursement was between 11 and 18 percent more for the remaining 2 drugs in 1995 and 4 drugs in 1996.

Medicare and its beneficiaries paid at least 20 percent more than the actual average wholesale price for over 80 percent of the 22 drugs. For every one of the 22 drugs reviewed, Medicare allowed more than the average actual price in both 1995 and 1996. Not only did Medicare pay more than the average price, the program allowed more than even the highest wholesale price obtained for every drug. Appendix B provides information on the highest and lowest wholesale price available for each drug in 1995 and 1996.

Based on the differences found between Medicare allowed amounts and actual wholesale prices, it is apparent that the current Medicare reimbursement methodology is based on an significantly inflated AWP statistic which bears little resemblance to actual wholesale prices available in the marketplace.

THERE IS NO CONSISTENCY AMONG CARRIERS IN ESTABLISHING AND UPDATING MEDICARE DRUG REIMBURSEMENT AMOUNTS.

Although Medicare's reimbursement methodology for prescription drugs does not provide for different payment rates based on geographical factors, the allowed amounts for individual drug codes varied among the carriers. Medicare guidelines allow carriers to update prescription drug reimbursement on a quarterly basis. However, not only did some carriers update yearly rather than quarterly but carrier allowed amounts for the same drug code differed within a single quarter.

For some drug codes, the differences in allowed amounts were significant. Carriers' allowed amounts varied even for single-source drugs where the reimbursement rate is based on only one AWP. A carrier reimbursed code J9217 (leuprolide acetate, a single-source drug) at $496.25 for all of 1995. Another carrier allowed $412.29 for the first quarter of 1995, $439.30 for the second and third quarters, and $477.50 for the fourth. For the first quarter of 1995, providers in one State were receiving 20 percent more in reimbursement than providers billing the same drug code in another State. The second carrier eventually paid $496.26 for this code in the first quarter of 1996. However, the first carrier increased reimbursement to $515.63 in the same quarter.

Little uniformity was found among carriers when comparing changes in reimbursement from the first quarter of 1995 to the second quarter of 1997. One carrier's reimbursement for code J9000 (doxorubicin hcl, 10 mg.) increased 128 percent from $20 to $45.50. Another carrier's rate for the same code decreased 19 percent from $48.20 to $39.10.

Since Medicare does not allow geographical differences to effect drug reimbursement, variations would seem to be caused by carriers' decisions regarding when to update reimbursement, what sources to use for documenting AWPs, and in the case of multiple-source drugs which generic drugs to include in calculating the median statistic.

RECOMMENDATIONS

The findings of this report provide evidence that Medicare and its beneficiaries are making excessive payments for prescription drugs. The published AWPs that are currently being used by Medicare-contracted carriers to determine reimbursement bear little or no resemblance to actual wholesale prices that are available to the physicians and suppliers that bill for these drugs. By basing reimbursement on published AWPs rather than more appropriate acquisition or wholesale prices, we estimate that Medicare and its beneficiaries paid nearly one billion dollars more for 22 drugs in 1995 and 1996.

We believe the information in this report provides further support for a previous recommendation made by the Office of Inspector General. **We recommended that HCFA reexamine its Medicare drug reimbursement methodologies, with the goal of reducing payments as appropriate.** The HCFA concurred with the recommendation. We urge readers to review our prior report, *Medicare Payments for Nebulizer Drugs*, which provided the full text of HCFA's comments on our recommendation.

For our readers' convenience, the options for changing Medicare's reimbursement methodology that appeared in the recommendation are presented below. We have modified the original discounted AWP and acquisition cost options in response to the evidence presented in this report concerning the large disparity between published AWPs and actual average wholesale prices available for prescription drugs.

Options for Changing Medicare's Reimbursement Methodology for Prescription Drugs

Discounted Wholesale Price

Beginning in January 1998, Medicare will reimburse prescription drugs at 95 percent of AWP. Many State Medicaid agencies use greater discounted AWPs to establish drug prices. Medicare could also base its drug payments on this larger discounted average wholesale prices. We believe that the 5 percent discount that will soon be implemented is not a large enough decrease. Upon implementation of this option, some type of general limit should be applied to the prices to ensure that inappropriate increases in average wholesale prices that could occur in subsequent years do not adversely affect Medicare payments. In addition, the Secretary should be granted the authority to conduct sample surveys of actual wholesale prices to determine the amount of difference between actual average wholesale prices and published AWPs. The percentage difference found in the sample could then be applied to all AWPs used by the program to determine drug reimbursement.

Acquisition Cost

Medicare could base the payment of drugs on either actual or estimated acquisition costs. Although Medicare currently has the authority to use EAC, carriers have yet to

successfully implement the option. Upon implementation of either the actual or estimated method, we believe that some type of general limit should be applied to ensure that inappropriate increases in drug prices do not occur in subsequent years.

Manufacturers' Rebates

Medicare could develop a legislative proposal to establish a mandated manufacturers' rebate program similar to Medicaid's rebate program. We recognize that HCFA does not have the authority to simply establish a mandated manufacturers' rebate program similar to the program used in Medicaid. Legislation was required to establish the Medicaid rebate program, and would also be required to establish a Medicare rebate program. We have not thoroughly assessed how a Medicare rebate program might operate, what administrative complexities it might pose, or how a Medicare rebate program might differ from a Medicaid rebate program. We believe, however, the legislative effort would be worthwhile. The same manufacturers that provide rebates to Medicaid make the drugs that are used by Medicare beneficiaries and paid for by the Medicare program.

To implement this option, HCFA would have to revise Medicare's claims coding system which does not identify the manufacturer or indicate if the drug is a brand name or a generic equivalent, information that is needed to discount the AWP and obtain a rebate for a specific drug. Medicaid uses National Drug Codes (NDC) in processing drug claims. The NDC identifies the manufacturer and reflects whether the drug is a brand name or a generic equivalent.

Competitive Bidding

Medicare could develop a legislative proposal to allow it to take advantage of its market position. While competitive bidding is not appropriate for every aspect of the Medicare program or in every geographic location, we believe that it can be effective in many instances, including the procurement of drugs. Medicare could ask pharmacies to compete for business to provide Medicare beneficiaries with prescription drugs. All types of pharmacies could compete for Medicare business, including independents, chains, and mail-order pharmacies.

Inherent Reasonableness

Since Medicare's guidelines for calculating reasonable charges for drugs result in excessive allowances, the Secretary can use her "inherent reasonableness" authority to set special reasonable charge limits. If this option is selected, however, it will not be effective unless the Secretary's authority to reduce inherently unreasonable payment levels is streamlined. The current inherent reasonableness process is resource intensive and time consuming, often taking two to four years to implement. Medicare faces substantial losses in potential savings--certainly in the millions of dollars--if reduced drug prices cannot be placed into effect quickly.

We also believe that the variance of Medicare reimbursement for individual drug codes among carriers is inappropriate. The rate at which physicians and suppliers are paid for drugs should not depend on which carrier providers bill. **We, therefore, recommend that HCFA require all carriers to reimburse a uniform allowed amount for each HCPCS drug code.** The HCFA could choose to supply all carriers with a list of average wholesale prices that it has determined represent each drug code. The carriers could then use the uniform prices to calculate payment. The HCFA could also designate one single entity to perform all necessary calculations to determine reimbursement for each drug code on a quarterly basis. All carriers would then use this standard reimbursement amount.

AGENCY COMMENTS

The HCFA concurred with our recommendations. The HCFA's proposal in the President's 1998 budget that would have required physicians to bill Medicare the actual acquisition cost for drugs was not adopted by Congress. However, the agency states that it will continue to pursue this policy in other appropriate ways. The full text of HCFA's comments are provided in Appendix D.

We support HCFA's continued pursuance of reducing drug payments where appropriate. We do not believe that the reimbursement methodology for prescription drugs recently adopted by Congress will curtail the excessive drug payments we've identified in the Medicare program. In this report we've identified Medicare allowances that were 11 to 900 percent greater than drug prices available to the physician and supplier communities.

To address the issue of uniformity among carriers, HCFA has convened a workgroup to develop an electronic file consisting of the average wholesale prices for drugs covered by Medicare. The agency reports it will distribute this file to Medicare contractors for their use in paying drug claims.

APPENDIX A

Description of 22 HCPCS Codes

Code	Description
J9217	Leuprolide Acetate (for depot suspension), 7.5 mg.
J7620	Albuterol Sulfate, 0.083%, per ml., inhalation solution administered through DME
J9265	Paclitaxel, 30 mg.
J9202	Goserelin Acetate Implant, per 3.6 mg.
J0640	Injection, Leucovorin Calcium, per 50 mg.
J9045	Carboplatin, 50 mg.
J1440	Injection, Filgrastim (G-CSF), per 300 mcg.
Q0136	Injection, Epoetin Alpha, (For Non-ESRD Use), per 1000 units
J2405	Injection, Ondansetron Hydrochloride, per 1 mg.
J1625	Injection, Granisetron Hydrochloride, per 1 mg.
J1561	Injection, Immune Globulin, Intravenous, per 500 mg.
J7670	Metaproterenol Sulfate, 0.4%, per 2.5 ml., inhalation solution administered through DME
J1441	Injection, Filgrastim (G-CSF), per 480 mcg.
J9182	Etoposide, 100 mg.
J9000	Doxorubicin HCL, 10 mg.
J9031	BCG (Intravesical) per instillation
J9181	Etoposide, 10 mg.
J7672	Metaproterenol Sulfate, 0.6%, per 2.5 ml., inhalation solution administered through DME
J9293	Injection, Mitoxantrone Hydrochloride, per 5 mg.
J9185	Fludarabine Phosphate, 50 mg.
J9010	Doxorubicin HCL, 50 mg. (code discontinued 12/31/96)
J3370	Injection, Vancomycin HCL, up to 500 mg. (code discontinued for infusion 9/1/96)

APPENDIX B

SUMMARY OF WHOLESALE PRICES AND ESTIMATED SAVINGS FOR 1995 AND 1996

SUMMARY OF WHOLESALE PRICES AND ESTIMATED SAVINGS FOR 1995

HCPCS Code	Average Medicare Allowed Amount	Actual Average Wholesale Price	Savings Based on Actual Average Wholesale Price	Lowest Wholesale Price Found	Savings Based on Lowest Wholesale Price	Highest Wholesale Price Found	Savings Based on Highest Wholesale Price
J9217	$474.67	$394.33	$83,728,802	$391.00	$87,202,882	$396.00	$81,991,762
J7620	$0.42	$0.15	$106,352,439	$0.12	$119,040,331	$0.21	$85,081,951
J9265	$180.82	$148.70	$14,425,220	$146.10	$15,592,891	$150.00	$13,841,385
J9202	$353.82	$292.95	$11,716,412	$286.84	$12,891,775	$296.00	$11,128,731
J0640	$23.27	$2.33	$61,175,769	$1.89	$62,449,291	$2.90	$59,499,161
J9045	$78.01	$66.67	$7,226,520	$64.90	$8,352,014	$67.55	$6,663,773
J1440	$149.46	$124.47	$8,620,001	$124.20	$8,711,972	$125.00	$8,436,058
Q0136	$11.92	$9.92	$7,942,246	$8.84	$12,246,366	$10.70	$4,850,833
J2405	$5.65	$4.33	$10,591,319	$3.91	$14,012,161	$5.31	$2,712,031
J1625	$165.29	$123.58	$9,709,625	$117.00	$11,240,029	$132.80	$7,562,405
J1561	$42.21	$16.12	$23,339,871	$9.33	$29,422,374	$32.11	$9,036,521
J7670	$1.22	$0.32	$23,986,743	$0.26	$25,544,703	$0.40	$21,872,652
J1441	$234.96	$195.50	$5,256,151	$188.90	$6,135,284	$198.80	$4,816,584
J9182	$131.25	$76.70	$11,660,930	$56.00	$16,085,515	$113.55	$3,783,570
J9000	$42.14	$13.12	$11,445,719	$10.90	$12,319,556	$14.70	$10,821,019
J9031	$155.20	$120.54	$3,659,236	$94.28	$6,430,898	$138.44	$1,769,236
J9181	$14.03	$7.80	$6,688,786	$5.60	$9,052,665	$11.36	$2,872,584
J7672	$1.22	$0.31	$11,560,517	$0.26	$12,175,863	$0.40	$10,400,217
J9293	$206.69	$127.49	$6,846,261	$123.23	$7,214,694	$132.01	$6,456,006
J9185	$173.03	$149.08	$1,890,949	$145.25	$2,193,648	$152.00	$1,660,634
J9010	$204.21	$64.86	$9,942,878	$52.00	$10,860,640	$73.50	$9,326,551
J3370	$10.07	$3.69	$7,235,171	$2.02	$9,122,193	$6.99	$3,491,965
TOTAL			$445,001,565		$498,297,745		$368,075,629

SUMMARY OF WHOLESALE PRICES AND ESTIMATED SAVINGS FOR 1996

HCPCS Code	Average Medicare Allowed Amount	Actual Average Wholesale Price	Savings Based on Actual Average Wholesale Price	Lowest Wholesale Price Found	Savings Based on Lowest Wholesale Price	Highest Wholesale Price Found	Savings Based on Highest Wholesale Price
J9217	$499.72	$414.73	$104,365,435	$409.27	$111,066,902	$421.00	$96,663,201
J7620	$0.41	$0.19	$92,199,355	$0.16	$105,604,026	$0.25	$67,530,255
J9265	$181.32	$148.56	$22,757,465	$140.26	$28,526,148	$155.43	$17,986,896
J9202	$378.29	$329.43	$11,215,983	$317.00	$14,067,894	$341.85	$8,364,073
J0640	$21.70	$2.81	$52,514,021	$2.39	$53,670,253	$3.45	$50,724,087
J9045	$82.76	$67.64	$12,539,724	$64.90	$14,814,584	$70.55	$10,128,000
J1440	$154.65	$123.39	$11,592,740	$121.56	$12,271,393	$126.00	$10,624,824
Q0136	$11.93	$10.37	$10,399,198	$9.31	$17,440,772	$10.70	$8,195,663
J2405	$6.08	$4.28	$14,319,348	$3.92	$17,172,050	$4.73	$10,776,959
J1625	$170.02	$125.71	$13,399,842	$122.90	$14,250,690	$128.00	$12,708,277
J1561	$42.21	$16.65	$24,808,622	$12.50	$28,833,317	$34.00	$7,967,739
J7670	$1.23	$0.41	$9,935,367	$0.32	$10,965,079	$0.51	$8,658,040
J1441	$246.34	$196.76	$8,470,488	$191.99	$9,285,542	$202.25	$7,532,512
J9182	$137.57	$70.91	$13,362,365	$37.06	$20,147,028	$112.57	$5,011,200
J9000	$44.19	$13.65	$12,480,751	$10.87	$13,616,851	$17.95	$10,723,475
J9031	$157.53	$133.13	$2,682,097	$112.00	$5,004,749	$148.95	$943,131
J9181	$14.14	$8.02	$5,909,155	$3.71	$10,077,601	$11.26	$2,784,899
J7672	$1.23	$0.44	$4,805,175	$0.32	$5,492,908	$0.55	$4,117,563
J9293	$172.81	$142.40	$2,712,650	$139.91	$2,935,141	$145.38	$2,447,586
J9185	$179.45	$156.50	$2,049,320	$152.00	$2,451,148	$161.00	$1,647,493
J9010	$207.12	$65.46	$10,513,722	$54.00	$11,364,260	$76.00	$9,731,464
J3370	$9.44	$4.42	$4,213,709	$3.45	$5,027,227	$6.45	$2,509,417
TOTAL			$447,246,532		$514,085,563		$357,776,754

APPENDIX C

INDIVIDUAL DRUG ALLOWANCES AND SAVINGS PERCENTAGES FOR 1995 AND 1996

Estimated Medicare Savings if Acquisition Costs Were Used for 1995 Prescription Drug Reimbursement

HCPCS Code	Drug Description	1995 Allowances	Estimated Savings	Percent Saved
J9217	Leuprolide Acetate	$455,238,461	$83,728,802	18%
J7620	Albuterol Sulfate 0.083%	$166,901,971	$106,352,439	64%
J9265	Paclitaxel	$79,672,417	$14,425,220	18%
J9202	Goserelin Acetate Implant	$65,806,263	$11,716,412	18%
J0640	Leucovorin Calcium	$64,687,013	$61,175,769	95%
J9045	Carboplatin	$49,306,732	$7,226,520	15%
J1440	Filgrastim, per 300 mcg.	$47,401,344	$8,620,001	18%
Q0136	Epoetin Alpha (Non-ESRD Use)	$47,324,218	$7,942,246	17%
J2405	Ondansetron Hydrochloride	$45,279,311	$10,591,319	23%
J1625	Granisetron Hydrochloride	$33,013,314	$9,709,625	29%
J1561	Immune Globulin	$31,646,866	$23,339,871	74%
J7670	Metaproterenol Sulfate 0.4%	$30,822,456	$23,986,743	78%
J1441	Filgrastim, per 480 mcg.	$29,865,814	$5,256,151	18%
J9182	Etoposide, 100 mg.	$25,713,304	$11,660,930	45%
J9000	Doxorubicin HCL, 10 mg.	$16,017,009	$11,445,719	71%
J9031	BCG (Intravesical)	$15,494,267	$3,659,236	24%
J9181	Etoposide, 10 mg.	$14,510,938	$6,688,786	46%
J7672	Metaproterenol Sulfate 0.6%	$13,876,217	$11,560,517	83%
J9293	Mitoxantrone Hydrochloride	$13,271,172	$6,846,261	52%
J9185	Fludarabine Phosphate	$12,725,400	$1,890,949	15%
J9010	Doxorubicin HCL, 50 mg.	$12,515,401	$9,942,878	79%
J3370	Vancomycin HCL	$12,051,885	$7,235,171	60%
TOTAL		$1,283,141,773	$445,001,565	35%

Estimated Medicare Savings if Acquisition Costs Were Used for 1996 Prescription Drug Reimbursement

HCPCS Code	Drug Description	1996 Allowances	Estimated Savings	Percent Saved
J9217	Leuprolide Acetate	$577,547,780	$104,365,435	18%
J7620	Albuterol Sulfate 0.083%	$175,399,846	$92,199,355	53%
J9265	Paclitaxel	$125,093,980	$22,757,465	18%
J9202	Goserelin Acetate Implant	$84,187,487	$11,215,983	13%
J0640	Leucovorin Calcium	$57,323,221	$52,514,021	92%
J9045	Carboplatin	$67,530,797	$12,539,724	19%
J1440	Filgrastim, per 300 mcg.	$54,460,250	$11,592,740	21%
Q0136	Epoetin Alpha (Non-ESRD Use)	$79,558,670	$10,399,198	13%
J2405	Ondansetron Hydrochloride	$47,331,513	$14,319,348	30%
J1625	Granisetron Hydrochloride	$49,691,403	$13,399,842	27%
J1561	Immune Globulin	$35,104,622	$24,808,622	71%
J7670	Metaproterenol Sulfate 0.4%	$14,203,070	$9,935,367	70%
J1441	Filgrastim, per 480 mcg.	$40,592,257	$8,470,488	21%
J9182	Etoposide, 100 mg.	$25,739,111	$13,362,365	52%
J9000	Doxorubicin HCL, 10 mg.	$17,410,833	$12,480,751	72%
J9031	BCG (Intravesical)	$16,544,398	$2,682,097	16%
J9181	Etoposide, 10 mg.	$13,381,243	$5,909,155	44%
J7672	Metaproterenol Sulfate 0.6%	$6,595,854	$4,805,175	73%
J9293	Mitoxantrone Hydrochloride	$14,522,607	$2,712,650	19%
J9185	Fludarabine Phosphate	$15,462,970	$2,049,320	13%
J9010	Doxorubicin HCL, 50 mg.	$14,541,250	$10,513,722	72%
J3370	Vancomycin HCL	$8,234,140	$4,213,709	51%
TOTAL		$1,540,457,302	$447,246,532	29%

APPENDIX D

HEALTH CARE FINANCING ADMINISTRATION COMMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

Deputy Administrator
Washington, D.C. 20201

DATE: OCT - 1 1997

TO: June Gibbs Brown
Inspector General

FROM: Nancy-Ann Min DeParle NMD
Deputy Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Excessive Medicare Payments for Prescription Drugs," (OEI-03-97-00290)

We reviewed the above-referenced report that examines Medicare payments for prescription drugs. Medicare allowances for prescription drugs increased 25 percent from $1.8 billion in 1995 to $2.3 billion in 1996. However, the number of services allowed increased only 9 percent between the 2 years.

Medicare does not pay for over-the-counter drugs or many prescription drugs that are self-administered. However, the program will pay for certain categories of drugs used by its beneficiaries. Contracted carriers determine the amounts that Medicare will pay for the drugs based on the lower of the estimated acquisition cost (EAC) or the national average wholesale price (AWP). The allowed amount is the price that Medicare and its beneficiaries pay a drug supplier. OIG findings indicate that at present, it is the AWP that carriers use to develop Medicare reimbursement for prescription drugs. The AWP is reported in The Red Book and other pricing publications and databases used by the pharmaceutical industry. The EAC is determined based on surveys of the actual invoice prices paid for the drug.

The findings contained in the report indicate that Medicare is making excessive payments for prescription drugs. The published AWPs currently used by Medicare carriers to determine reimbursement do not resemble the actual wholesale prices which are available to the physician and supplier communities that bill for these drugs.

OIG suggests that the Health Care Financing Administration (HCFA): (1) reexamine its Medicare drug reimbursement methodologies, with the goal of reducing payments; and (2) require all carriers to reimburse a uniform allowed amount for each HCFA Common Procedural Coding System (HCPCS) drug code.

HCFA concurs with OIG's recommendations. Our detailed comments are as follows:

OIG Recommendation 1

HCFA should require all carriers to reimburse a uniform allowed amount for each HCPCS drug code.

HCFA Response

We concur. HCFA agrees with OIG's findings and recommendations contained in this report. HCFA convened a workgroup to develop an electronic file consisting of the AWPs for drugs covered by Medicare. HCFA will then distribute this file to Medicare contractors for their use in paying claims for drugs.

OIG Recommendation 2

HCFA should reexamine its Medicare drug reimbursement methodologies, with the goal of reducing payments as appropriate.

HCFA Response

We concur. We agree with OIG's findings and recommendations. We included a provision in the President's 1998 budget bill that would have eliminated the markup for drugs billed to Medicare by requiring physicians to bill the program the actual acquisition cost for drugs. Unfortunately, this provision was not enacted, but we will pursue this policy in other appropriate ways.

EXHIBIT 102

UNITED STATES PUBLIC LAWS
101st Congress - Second Session
Convening January 23, 1990

Additions and Deletions are not identified in this document.
For Legislative History of Act, see LH database or Report for
this Public Law in U.S.C.C. & A.N. Legislative History section.

<< STATUTES-AT-LARGE PAGE BREAKS ARE NOT YET AVAILABLE FOR THIS DOCUMENT >>

PL 101-508 (HR 5835)
November 5, 1990
OMNIBUS BUDGET RECONCILIATION ACT OF 1990

An Act to provide for reconciliation pursuant to section 4 of the concurrent resolution on the budget for fiscal year 1991.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Omnibus Budget Reconciliation Act of 1990".

SEC. 2. TABLE OF TITLES.

Title VIII. Veterans' programs.

Title IX. Transportation.

Title X. Miscellaneous user fees and other provisions.

Title XI. Revenue provisions.

Title XII. Pensions.

Title XIII. Budget enforcement.

PART 1--REDUCTIONS IN SPENDING

SEC. 4401. REIMBURSEMENT FOR PRESCRIBED DRUGS.

(a) In General.--

<< 42 USCA § 1396b >>

(1) Denial of federal financial participation unless rebate agreements and drug use review in effect.--Section 1903(i) (42 U.S.C. 1396b(i)) is amended--

(A) by striking the period at the end of paragraph (9) and inserting "; or", and

(B) by inserting after paragraph (9) the following new paragraph:

"(10) with respect to covered outpatient drugs of a manufacturer dispensed in any State unless, (A) except as provided in section 1927(a)(3), the manufacturer complies with the rebate requirements of section 1927(a) with respect to the drugs so dispensed in all States, and (B) effective January 1, 1993, the State provides for drug use review in accordance with section 1927(g).".

<< 42 USCA § 1396a >>

(2) Prohibiting state plan drug access limitations for drugs covered under a rebate agreement.--Section 1902(a) of such Act (42 U.S.C. 1396a(a)) is amended--

(A) by striking "and" at the end of paragraph (52),

(B) by striking the period at the end of paragraph (53) and inserting "; and", and

(C) by inserting after paragraph (53) the following new paragraph:

"(54)(A) provide that, any formulary or similar restriction (except as provided in section 1927(d)) on the coverage of covered outpatient drugs under the plan shall permit the coverage of covered outpatient drugs of any manufacturer which has entered into and complies with an agreement under section 1927(a), which are prescribed for a medically accepted indication (as defined in subsection 1927(k)(6)), and

"(B) comply with the reporting requirements of section 1927(b)(2)(A) and the requirements of subsections (d) and (g) of section 1927.".

<< 42 USCA § 1396r-8 >>

<< 42 USCA § 1396s >>

(3) Rebate agreements for covered outpatient drugs, drug use review, and related provisions.--Title XIX of the Social Security Act is amended by redesignating section 1927 as section 1928 and by inserting after section 1926 the following new section:

"payment for covered outpatient drugs

"Sec. 1927. (a) Requirement for Rebate Agreement.--

"(1) In general.--In order for payment to be available under section 1903(a) for covered

outpatient drugs of a manufacturer, the manufacturer must have entered into and have in effect a rebate agreement described in subsection (b) with the Secretary, on behalf of States (except that, the Secretary may authorize a State to enter directly into agreements with a manufacturer). Any agreement between a State and a manufacturer prior to April 1, 1991, shall be deemed to have been entered into on January 1, 1991, and payment to such manufacturer shall be retroactively calculated as if the agreement between the manufacturer and the State had been entered into on January 1, 1991. If a manufacturer has not entered into such an agreement before March 1, 1991, such an agreement, subsequently entered into, shall not be effective until the first day of the calendar quarter that begins more than 60 days after the date the agreement is entered into.

"(2) Effective date.--Paragraph (1) shall first apply to drugs dispensed under this title on or after January 1, 1991.

"(3) Authorizing payment for drugs not covered under rebate agreements.-- Paragraph (1), and section 1903(1)(10)(A), shall not apply to the dispensing of a single source drug or innovator multiple source drug if (A)(i) the State has made a determination that the availability of the drug is essential to the health of beneficiaries under the State plan for medical assistance; (ii) such drug has been given a rating of 1-A by the Food and Drug Administration; and (iii)(I) the physician has obtained approval for use of the drug in advance of its dispensing in accordance with a prior authorization program described in subsection (d), or (II) the Secretary has reviewed and approved the State's determination under subparagraph (A); or (B) the Secretary determines that in the first calendar quarter of 1991, there were extenuating circumstances.

"(4) Effect on existing agreements.--In the case of a rebate agreement in effect between a State and a manufacturer on the date of the enactment of this section, such agreement, for the initial agreement period specified therein, shall be considered to be a rebate agreement in compliance with this section with respect to that State, if the State agrees to report to the Secretary any rebates paid pursuant to the agreement and such agreement provides for a minimum aggregate rebate of 10 percent of the State's total expenditures under the State plan for coverage of the manufacturer's drugs under this title. If, after the initial agreement period, the State establishes to the satisfaction of the Secretary that an agreement in effect on the date of the enactment of this section provides for rebates that are at least as large as the rebates otherwise required under this section, and the State agrees to report any rebates under the agreement to the Secretary, the agreement shall be considered to be a rebate agreement in compliance with the section for the renewal periods of such agreement.

"(b) Terms of Rebate Agreement.--

"(1) Periodic rebates.--

"(A) In general.--A rebate agreement under this subsection shall require the manufacturer to provide, to each State plan approved under this title, a rebate each calendar quarter (or periodically in accordance with a schedule specified by the Secretary) in an amount specified in subsection (c) for covered outpatient drugs of the manufacturer dispensed under the plan during the quarter (or such other period as the Secretary may specify). Such rebate shall be paid by the manufacturer not later than 30 days after the date of receipt of the information described in paragraph (2) for the period involved.

"(B) Offset against medical assistance.--Amounts received by a State under this section (or under an agreement authorized by the Secretary under subsection (a)(1) or

an agreement described in subsection (a)(4)) in any quarter shall be considered to be a reduction in the amount expended under the State plan in the quarter for medical assistance for purposes of section 1903(a)(1).

"(2) State provision of information.--

"(A) State responsibility.--Each State agency under this title shall report to each manufacturer not later than 60 days after the end of each calendar quarter and in a form consistent with a standard reporting format established by the Secretary, information on the total number of dosage units of each covered outpatient drug dispensed under the plan during the quarter, and shall promptly transmit a copy of such report to the Secretary.

"(B) Audits.--A manufacturer may audit the information provided (or required to be provided) under subparagraph (A). Adjustments to rebates shall be made to the extent that information indicates that utilization was greater or less than the amount previously specified.

"(3) Manufacturer provision of price information.--

"(A) In general.--Each manufacturer with an agreement in effect under this section shall report to the Secretary--

"(i) not later than 30 days after the last day of each quarter (beginning on or after January 1, 1991), on the average manufacturer price (as defined in subsection (k)(1)) and, (for single source drugs and innovator multiple source drugs), the manufacturer's best price (as defined in subsection (c)(2)(B)) for covered outpatient drugs for the quarter, and

"(ii) not later than 30 days after the date of entering into an agreement under this section on the average manufacturer price (as defined in subsection (k)(1)) as of October 1, 1990 for each of the manufacturer's covered outpatient drugs.

"(B) Verification surveys of average manufacturer price.--The Secretary may survey wholesalers and manufacturers that directly distribute their covered outpatient drugs, when necessary, to verify manufacturer prices reported under subparagraph (A). The Secretary may impose a civil monetary penalty in an amount not to exceed $100,000 on a wholesaler, manufacturer, or direct seller, if the wholesaler, manufacturer, or direct seller of a covered outpatient drug refuses a request for information about charges or prices by the Secretary in connection with a survey under this subparagraph or knowingly provides false information. The provisions of section 1128A (other than subsections (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

"(C) Penalties.--

"(i) Failure to provide timely information.--In the case of a manufacturer with an agreement under this section that fails to provide information required under subparagraph (A) on a timely basis, the amount of the penalty shall be increased by $10,000 for each day in which such information has not been provided and such amount shall be paid to the Treasury, and, if such information is not reported within 90 days of the deadline imposed, the agreement shall be suspended for services furnished after the end of such 90-day period and until the date such information is reported (but in no case

shall such suspension be for a period of less than 30 days).

"(ii) False information.--Any manufacturer with an agreement under this section that knowingly provides false information is subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information. Such civil money penalties are in addition to other penalties as may be prescribed by law. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

"(D) Confidentiality of information.--Notwithstanding any other provision of law, information disclosed by manufacturers or wholesalers under this paragraph is confidential and shall not be disclosed by the Secretary or a State agency (or contractor therewith) in a form which discloses the identity of a specific manufacturer or wholesaler, prices charged for drugs by such manufacturer or wholesaler, except as the Secretary determines to be necessary to carry out this section and to permit the Comptroller General to review the information provided.

"(4) Length of agreement.--

"(A) In general.--A rebate agreement shall be effective for an initial period of not less than 1 year and shall be automatically renewed for a period of not less than one year unless terminated under subparagraph (B).

"(B) Termination.--

"(i) By the secretary.--The Secretary may provide for termination of a rebate agreement for violation of the requirements of the agreement or other good cause shown. Such termination shall not be effective earlier than 60 days after the date of notice of such termination. The Secretary shall provide, upon request, a manufacturer with a hearing concerning such a termination, but such hearing shall not delay the effective date of the termination.

"(ii) By a manufacturer.--A manufacturer may terminate a rebate agreement under this section for any reason. Any such termination shall not be effective until such period after the date of the notice as the Secretary may provide (but not beyond the term of the agreement).

"(iii) Effectiveness of termination.--Any termination under this subparagraph shall not affect rebates due under the agreement before the effective date of its termination.

"(C) Delay before reentry.--In the case of any rebate agreement with a manufacturer under this section which is terminated, another such agreement with the manufacturer (or a successor manufacturer) may not be entered into until a period of 1 calendar quarter has elapsed since the date of the termination, unless the Secretary finds good cause for an earlier reinstatement of such an agreement.

"(c) Amount of Rebate.--

"(1) Basic rebate for single source drugs and innovator multiple source drugs.--With respect to single source drugs and innovator multiple source drugs, each manufacturer shall remit a basic rebate to the State medical assistance plan. Except as otherwise provided in this subsection, the amount of the rebate to a State for a calendar quarter (or other period specified by the Secretary) with respect to each dosage form and strength

of single source drugs and innovator multiple source drugs shall be equal to the product of--

"(A) the total number of units of each dosage form and strength dispensed under the plan under this title in the quarter (or other period) reported by the State under subsection (b)(2); and

"(B)(1) for quarters (or periods) beginning after December 31, 1990, and before January 1, 1993, the greater of--

"(I) the difference between the average manufacturer price (after deducting customary prompt payment discounts) and 87.5 percent of such price for the quarter (or other period), or

"(II) the difference between the average manufacturer price for a drug and the best price (as defined in paragraph (2)(B)) for such quarter (or period) for such drug (except that for calendar quarters beginning after December 31, 1990, and ending before January 1, 1992, the rebate shall not exceed 25 percent of the average manufacturer price, and for calendar quarters beginning after December 31, 1991, and ending before January 1, 1993, the rebate shall not exceed 50 percent of the average manufacturer price); and

"(ii) for quarters (or other periods) beginning after December 31, 1992, the greater of--

"(I) the difference between the average manufacturer price for a drug and 85 percent of such price, or

"(II) the difference between the average manufacturer price for a drug and the best price (as defined in paragraph (2)(B)) for such quarter (or period) for such drug.

"(C) For the purposes of this paragraph, the term 'best price' means, with respect to a single source drug or innovator multiple source drug of a manufacturer, the lowest price available from the manufacturer to any wholesaler, retailer, nonprofit entity, or governmental entity within the United States (excluding depot prices and single award contract prices, as defined by the Secretary, of any agency of the Federal Government). The best price shall be inclusive of cash discounts, free goods, volume discounts, and rebates (other than rebates under this section) and shall be determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package, and shall not take into account prices that are merely nominal in amount;

"(D) In the case of a covered outpatient drug approved for marketing after October 1, 1990, any reference in this paragraph to 'October 1, 1990' shall be a reference to the first day of the first month during which the drug was marketed.

"(2) Additional rebate for single source and innovator multiple source drugs.--(A) Each manufacturer shall remit an additional rebate to the State medical assistance plan in an amount equal to:

"(i) For calendar quarters (or other periods) beginning after December 31, 1990 and ending before January 1, 1994--

"(I) the total number of each dosage form and strength of a single source or innovator multiple source drug dispensed during the calendar quarter (or other period); multiplied by

"(II)(aa) the average manufacturer price for each dosage form and strength, minus

"(bb) the average manufacturer price for each such dosage form and strength in effect on October 1, 1990, increased by the percentage increase in the Consumer Price Index for all urban consumers (U.S. average) from October 1, 1990, to the month before the beginning of the calendar quarter (or other period) involved;

"(ii) For calendar quarters (or other periods) beginning after December 31, 1993--

"(I) the total number of each dosage form and strength of a single source or innovative multiple source drug dispensed during the calendar quarter (or other period); multiplied by

"(II) the amount, if any, by which the weighted average manufacturer price for single source and innovator multiple source drugs of a manufacturer exceeds the weighted average manufacturer price for the manufacturer as of October 1, 1990, increased by the percentage increase in the Consumer Price Index for all urban consumers (U.S. average) from October 1, 1990, to the month before the beginning of the calendar quarter (or other period) involved.

"(B)(i) For the purposes of subparagraph (A)(ii), the term 'weighted average manufacturer price' means (with respect to a calendar quarter or other period) the ratio of--

"(I) the sum of the products (for all covered drugs of the manufacturer purchased under a State program under this title) of--

"(aa) the average manufacturer price for each such covered drug; and

"(bb) the number of units of the covered drug sold to any State program under this title during such period, to

"(II) the total number of units of all such covered drugs sold under a State program under this title in such period,

except that the Secretary may exclude certain new drugs from the calculation of the weighted average if the inclusion of any such drug in such calculation has the effect of--

"(aa) reducing the rebate otherwise calculated pursuant to subparagraph (A)(ii); or

"(bb) increasing the rebate otherwise calculated pursuant to subparagraph (A)(ii) (in cases where such calculation under the conditions outlined in clause (ii).

"(ii)(I) The Secretary may exclude drugs approved by the Food and Drug Administration on or after October 1, 1990, from the calculation of weighted average manufacturer price if inclus manufacturer demonstrates through a petition, in a form and manner prescribed by the Secretary, undue hardship on such manufacturer as a result of the inclusion of such drug in such calculation).

"(II) The Secretary may promulgate guidelines to restrict the conditions under which the Secretary may consider such petitions.

"(C) For each of 8 calendar quarters beginning after December 31, 1991, the Secretary shall compare the aggregate amount of the rebates under subparagraph (A)(i) to the aggregate amount of rebates under subparagraph (A)(ii). Based on any such comparison, the Secretary may propose and utilize an alternative **formula** for the purpose of calculating an aggregate rebate.

"(3) Rebate for other **drugs**.--The amount of the rebate to a State for a calendar quarter (or other period specified by the Secretary) with respect to covered outpatient **drugs** (other than single source **drugs** and innovator multiple source **drugs**) shall be equal to the product of--

"(A) the applicable percentage (as described in paragraph (4) of the average manufacturer price for each dosage form and strength of such **drugs** (after deducting customary prompt payment discounts) for the quarter (or other period), and

"(B) the number of units of such form and dosage dispensed under the plan under this title in the quarter (or other period) reported by the State under subsection (b)(2).

"(4) For the purposes of paragraph (3), the applicable percentage is--

"(A) with respect to calendar quarters beginning after December 31, 1990, and ending before January 1, 1994, 10 percent; and

"(B) with respect to calendar quarters beginning on or after December 31, 1993, 11 percent.

"(d) Limitations on Coverage of Drugs.--

"(1) Permissable restrictions.--(A) Except as provided in paragraph (6), a State may subject to prior authorization any covered outpatient drug. Any such prior authorization program shall comply with the requirements of paragraph (5).

"(B) A State may exclude or otherwise restrict coverage of a covered outpatient drug if--

"(i) the prescribed use is not for a medically accepted indication (as defined in (k)(6));

"(ii) the drug is contained in the list referred to in paragraph (2); or

"(iii) the drug is subject to such restrictions pursuant to an agreement between a manufacturer and a State authorized by the Secretary under subsection (a)(1) or in effect pursuant to subsection (a)(4).

"(2) List of drugs subject to restriction.--The following drugs or classes of drugs, or their medical uses, may be excluded from coverage or otherwise restricted:

"(A) Agents when used for anorexia or weight gain.

"(B) Agents when used to promote fertility.

"(C) Agents when used for cosmetic purposes or hair growth.

"(D) Agents when used for the symptomatic relief of cough and colds.

"(E) Agents when used to promote smoking cessation.

"(F) Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.

"(G) Nonprescription drugs.

"(H) Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.

"(I) Drugs described in section 107(c)(3) of the Drug Amendments of 1962 and identical, similar, or related drugs (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations ('DESI' drugs)).

"(J) Barbiturates.

"(K) Benzodiazepines.

"(3) Update of Drug Listings.--The Secretary shall (except with respect to new drugs approved by the FDA for the first 6 months following the date of approval of such drugs shall not be subject to being listed in paragraph (2) under the provisions of this paragraph), by regulation, periodically update the list of drugs described in paragraph (2) or classes of drugs, or their medical uses, which the Secretary has determined, based on data collected by surveillance and utilization review programs of State medical assistance programs, to be subject to clinical abuse or inappropriate use.

"(4) Innovator multiple-source drugs.--Innovator multiple-source drugs shall be treated under applicable State and Federal law and regulation.

"(5) Prior authorization programs.--A State plan under this title may not require, as a condition of coverage or payment for a covered outpatient drug for which Federal financial participation is available in accordance with this section, the approval of the drug before its dispensing for any medically accepted indication (as defined in subsection (k)(6)) unless the system providing for such approval--

"(A) provides response by telephone or other telecommunication device within 24 hours of a request for prior authorization; and

"(B) except with respect to the drugs on the list referred to in paragraph (2), provides for the dispensing of at least a 72-hour supply of a covered outpatient prescription drug in an emergency situation (as defined by the Secretary).

"(6) Treatment of new drugs.--A State may not exclude for coverage, subject to prior authorization, or otherwise restrict any new biological or drug approved by the Food and Drug Administration after the date of enactment of this section, for a period of 6 months after such approval.

"(7) Other permissible restrictions.--A State may impose limitations, with respect to all such drugs in a therapeutic class, on the minimum or maximum quantities per prescription or on the number of refills, provided such limitations are necessary to discourage waste.

Nothing in this section shall restrict the ability of a State to address individual instances of fraud or abuse in any manner authorized under the Social Security Act.

"(8) Delayed effective date.--The provisions of paragraph (5) shall become effective with respect to drugs dispensed under this title on or after July 1, 1991.

"(e) Denial of Federal Financial Participation in Certain Cases.--The Secretary shall provide that no payment shall be made to a State under section 1903(a) for an innovator multiple-source **drug** dispensed on or after July 1, 1991, if, under applicable State law, a less expensive noninnovator multiple source **drug** (other than the innovator multiple-source **drug**) could have been dispensed.

"(f) Pharmacy **Reimbursement**.--

"(1) No reductions in **reimbursement limits**.--(A) During the period of time beginning on January 1, 1991, and ending on December 31, 1994, the Secretary may not **modify** by regulation the **formula** used to determine **reimbursement limits** described in the regulations under 42 CFR 447.331 through 42 CFR 447.334 (as in effect on the date of the enactment of the Omnibus Budget Reconciliation Act of 1990) to reduce such **limits** for covered outpatient **drugs**.

(B) During the period of time described in subparagraph (A), any State that was in compliance with the regulations described in subparagraph (A) may not reduce the **limits** for covered outpatient **drugs** described in subparagraph (A) or dispensing fees for such **drugs**.

"(2) Establishment of upper payment **limits**.--HCFA shall establish a Federal upper **reimbursement limit** for each multiple source **drug** for which the FDA has rated three or more products therapeutically and pharmaceutically equivalent, regardless of whether all such additional formulations are rated as such and shall use only such formulations when determining any such upper **limit**.

"(g) **Drug** Use Review.--

"(1) In general.--

"(A) In order to meet the requirement of section 1903(1)(10)(B), a State shall provide, by not later than January 1, 1993, for a **drug** use review program described in paragraph (2) for covered outpatient **drugs** in order to assure that prescriptions (i) are appropriate, (ii) are medically necessary, and (iii) are not likely to result in adverse medical results. The program shall be designed to educate physicians and pharmacists to identify and reduce the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care, among physicians, pharmacists, and patients, or associated with specific drugs or groups of drugs, as well as potential and actual severe adverse reactions to drugs including education on therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse.

"(B) The program shall assess data on drug use against predetermined standards, consistent with the following:

"(i) compendia which shall consist of the following:

"(I) American Hospital Formulary Service Drug Information;

"(II) United States Pharmacopeia-Drug Information; and

"(III) American Medical Association Drug Evaluations; and

"(ii) the peer-reviewed medical literature.

"(C) The Secretary, under the procedures established in section 1903, shall pay to each State an amount equal to 75 per centum of so much of the sums expended by the State plan during calendar years 1991 through 1993 as the Secretary determines is attributable to the statewide adoption of a drug use review program which conforms to the requirements of this subsection.

"(D) States shall not be required to perform additional drug use reviews with respect to drugs dispensed to residents of nursing facilities which are in compliance with the drug regimen review procedures prescribed by the Secretary for such facilities in regulations implementing section 1919, currently at section 493.60 of title 42, Code of Federal Regulations.

"(2) Description of program.--Each drug use review program shall meet the following requirements for covered outpatient drugs:

"(A) Prospective drug review.--(i) The State plan shall provide for a review of drug therapy before each prescription is filled or delivered to an individual receiving benefits under this title, typically at the point-of-sale or point of distribution. The review shall include screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions (including serious interactions with nonprescription or over-the-counter drugs), incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse. Each State shall use the compendia and literature referred to in paragraph (1)(B) as its source of standards for such review.

"(ii) As part of the State's prospective drug use review program under this subparagraph applicble State law shall establish standards for counseling of individuals receiving benefits under this title by pharmacists which includes at least the following: ¶ I28 "(I) The pharmacist must offer to discuss with each individual receiving benefits under this title or caregiver of such individual (in person, whenever practicable, or through access to a telephone service which is toll-free for long-distance calls) who presents a prescription, matters which in the exercise of the pharmacist's professional judgment (consistent with State law respecting the provision of such information), the pharmacist deems significant including the following:

"(aa) The name and description of the medication.

"(bb) The route, dosage form, dosage, route of administration, and duration of drug therapy.

"(cc) Special directions and precautions for preparation, administration and use by the patient.

"(dd) Common severe side or adverse effects or interactions and therapeutic

contraindications that may be encountered, including their avoidance, and the action required if they occur.

"(ee) Techniques for self-monitoring drug therapy.

"(ff) Proper storage.

"(gg) Prescription refill information.

"(hh) Action to be taken in the event of a missed dose.

"(II) A reasonable effort must be made by the pharmacist to obtain, record, and maintain at least the following information regarding individuals receiving benefits under this title:

"(aa) Name, address, telephone number, date of birth (or age) and gender.

"(bb) Individual history where significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices.

"(cc) Pharmacist comments relevant to the individuals drug therapy. Nothing in this clause shall be construed as requiring a pharmacist to provide consultation when an individual receiving benefits under this title or caregiver of such individual refuses such consultation.

"(B) Retrospective drug use review.--The program shall provide, through its mechanized drug claims processing and information retrieval systems (approved by the Secretary under section 1903(r)) or otherwise, for the ongoing periodic examination of claims data and other records in order to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care, among physicians, pharmacists and individuals receiving benefits under this title, or associated with specific drugs or groups of drugs.

"(C) Application of standards.--The program shall, on an ongoing basis, assess data on drug use against explicit predetermined standards (using the compendia and literature referred to in subsection (1)(B) as the source of standards for such assessment) including but not limited to monitoring for therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, and clinical abuse/misuse and, as necessary, introduce remedial strategies, in order to improve the quality of care and to conserve program funds or personal expenditures.

"(D) Educational program.--The program shall, through its State drug use review board established under paragraph (3), either directly or through contracts with accredited health care educational institutions, State medical societies or State pharmacists associations/societies or other organizations as specified by the State, and using data provided by the State drug use review board on common drug therapy problems, provide for active and ongoing educational outreach programs (including the activities described in paragraph (3)(C)(iii) of this subsection) to educate practitioners on common drug therapy problems with the aim of improving prescribing or dispensing practices.

"(3) State drug use review board.--

"(A) Establishment.--Each State shall provide for the establishment of a drug use review board (hereinafter referred to as the 'DUR Board') either directly or through a contract with a private organization.

"(B) Membership.--The membership of the DUR Board shall include health care professionals who have recognized knowledge and expertise in one or more of the following:

"(i) The clinically appropriate prescribing of covered outpatient drugs.

"(ii) The clinically appropriate dispensing and monitoring of covered outpatient drugs.

"(iii) Drug use review, evaluation, and intervention.

"(iv) Medical quality assurance.

The membership of the DUR Board shall be made up at least 1/3 but no more than 51 percent licensed and actively practicing physicians and at least 1/3 * * * licensed and actively practicing pharmacists.

"(C) Activities.--The activities of the DUR Board shall include but not be limited to the following:

"(i) Retrospective DUR as defined in section (2)(B).

"(ii) Application of standards as defined in section (2)(C).

"(iii) Ongoing interventions for physicians and pharmacists, targeted toward therapy problems or individuals identified in the course of retrospective drug use reviews performed under this subsection. Intervention programs shall include, in appropriate instances, at least:

"(I) information dissemination sufficient to ensure the ready availability to physicians and pharmacists in the State of information concerning its duties, powers, and basis for its standards;

"(II) written, oral, or electronic reminders containing patient-specific or drug-specific (or both) information and suggested changes in prescribing or dispensing practices, communicated in a manner designed to ensure the privacy of patient-related information;

"(III) use of face-to-face discussions between health care professionals who are experts in rational drug therapy and selected prescribers and pharmacists who have been targeted for educational intervention, including discussion of optimal prescribing, dispensing, or pharmacy care practices, and follow-up face-to-face discussions; and

"(IV) intensified review or monitoring of selected prescribers or dispensers.

The Board shall re-evaluate interventions after an appropriate period of time to determine if the intervention improved the quality of drug therapy, to evaluate the success of the interventions and make modifications as necessary.

"(D) Annual report.--Each State shall require the DUR Board to prepare a report on

an annual basis. The State shall submit a report on an annual basis to the Secretary which shall include a description of the activities of the Board, including the nature and scope of the prospective and retrospective drug use review programs, a summary of the interventions used, an assessment of the impact of these educational interventions on quality of care, and an estimate of the cost savings generated as a result of such program. The Secretary shall utilize such report in evaluating the effectiveness of each State's drug use review program.

"(h) Electronic Claims Management.--

"(1) In general.--In accordance with chapter 35 of title 44, United States Code (relating to coordination of Federal information policy), the Secretary shall encourage each State agency to establish, as its principal means of processing claims for covered outpatient drugs under this title, a point-of-sale electronic claims management system, for the purpose of performing on-line, real time eligibility verifications, claims data capture, adjudication of claims, and assisting pharmacists (and other authorized persons) in applying for and receiving payment.

"(2) Encouragement.--In order to carry out paragraph (1)--

"(A) for calendar quarters during fiscal years 1991 and 1992, expenditures under the State plan attributable to development of a system described in paragraph (1) shall receive Federal financial participation under section 1903(a)(3)(A)(i) (at a matching rate of 90 percent) if the State acquires, through applicable competitive procurement process in the State, the most cost-effective telecommunications network and automatic data processing services and equipment; and

"(B) the Secretary may permit, in the procurement described in subparagraph (A) in the application of part 433 of title 42, Code of Federal Regulations, and parts 95, 205, and 307 of title 45, Code of Federal Regulations, the substitution of the State's request for proposal in competitive procurement for advance planning and implementation documents otherwise required.

"(i) Annual Report.--

"(1) In general.--Not later than May 1 of each year the Secretary shall transmit to the Committee on Finance of the Senate, the Committee on Energy and Commerce of the House of Representatives, and the Committees on Aging of the Senate and the House of Representatives a report on the the operation of this section in the preceding fiscal year.

"(2) Details.--Each report shall include information on--

"(A) ingredient costs paid under this title for single source drugs, multiple source drugs, and nonprescription covered outpatient drugs;

"(B) the total value of rebates received and number of manufacturers providing such rebates;

"(C) how the size of such rebates compare with the size or rebates offered to other purchasers of covered outpatient drugs;

"(D) the effect of inflation on the value of rebates required under this section;

"(E) trends in prices paid under this title for covered outpatient drugs; and

"(F) Federal and State administrative costs associated with compliance with the provisions of this title.

"(j) Exemption of Organized Health Care Settings.--(1) Covered outpatient drugs dispensed by * * * Health Maintenance Organizations, including those organizations that contract under section 1903(m), are not subject to the requirements of this section.

"(2) The State plan shall provide that a hospital (providing medical assistance under such plan) that dispenses covered outpatient drugs using drug formulary systems, and bills the plan no more than the hospital's purchasing costs for covered outpatient drugs (as determined under the State plan) shall not be subject to the requirements of this section.

"(3) Nothing in this subsection shall be construed as providing that amounts for covered outpatient drugs paid by the institutions described in this subsection should not be taken into account for purposes of determining the best price as described in subsection (c).

"(k) Definitions.--In this section--

"(1) Average manufacturer price.--The term 'average manufacturer price' means, with respect to a covered outpatient drug of a manufacturer for a calendar quarter, the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade.

"(2) Covered outpatient drug.--Subject to the exceptions in paragraph (3), the term 'covered outpatient drug' means--

"(A) of those drugs which are treated as prescribed drugs for purposes of section 1905(a)(12), a drug which may be dispensed only upon prescription (except as provided in paragraph (5)), and--

"(i) which is approved for safety and effectiveness as a prescription drug under section 505 or 507 of the Federal Food, Drug, and Cosmetic Act or which is approved under section 505(j) of such Act;

"(ii)(I) which was commercially used or sold in the United States before the date of the enactment of the Drug Amendments of 1962 or which is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and

(II) which has not been the subject of a final determination by the Secretary that it is a 'new drug' (within the meaning of section 201(b) of the Federal Food, Drug, and Cosmetic Act) or an action brought by the Secretary under section 301, 302(a), or 304(a) of such Act to enforce section 502(f) or 505(a) of such Act; or

"(iii)(I) which is described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined there is a compelling justification for its medical need, or is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) for which the Secretary has not issued a notice of an opportunity for a hearing under section 505(e) of the Federal Food, Drug, and Cosmetic Act on a proposed order of the

Secretary to withdraw approval of an application for such drug under such section because the Secretary has determined that the drug is less than effective for some or all conditions of use prescribed, recommended, or suggested in its labeling; and

"(B) a biological product, other than a vaccine which--

"(i) may only be dispensed upon prescription,

"(ii) is licensed under section 351 of the Public Health Service Act, and

"(iii) is produced at an establishment licensed under such section to produce such product; and

"(C) insulin certified under section 506 of the Federal Food, Drug, and Cosmetic Act.

"(3) Limiting definition.--The term 'covered outpatient drug' does not include any drug, biological product, or insulin provided as part of, or as incident to and in the same setting as, any of the following (and for which payment may be made under this title as part of payment for the following and not as direct **reimbursement** for the **drug**):

"(A) Inpatient hospital services.

"(B) Hospice services.

"(C) Dental services, except that **drugs** for which the State plan authorizes direct **reimbursement** to the dispensing dentist are covered outpatient **drugs**.

"(D) Physicians' services.

"(E) Outpatient hospital services * * * * emergency room visits.

"(F) Nursing facility services.

"(G) Other laboratory and x-ray services.

"(H) Renal dialysis.

Such term also does not include any such **drug** or product which is used for a medical indication which is not a medically accepted indication.

"(4) Nonprescription **drugs**.--If a State plan for medical assistance under this title includes coverage of prescribed **drugs** as described in section 1905(a)(12) and permits coverage of **drugs** which may be sold without a prescription (commonly referred to as 'over-the-counter' **drugs**), if they are prescribed by a physician (or other person authorized to prescribe under State law), such a **drug** shall be regarded as a covered outpatient **drug**.

"(5) Manufacturer.--The term 'manufacturer' means any entity which is engaged in--

"(A) the production, preparation, propagation, compounding, conversion, or processing of prescription **drug** products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or

"(B) in the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products.

Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.

"(6) Medically accepted indication.--The term 'medically accepted indication' means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act, which appears in peer-reviewed medical literature or which is accepted by one or more of the following compendia: the American Hospital Formulary Service-Drug Information, the American Medical Association Drug Evaluations, and the United States Pharmacopeia-Drug Information.

"(7) Multiple source drug; innovator multiple source drug; noninnovator multiple source drug; single source drug.--

"(A) Defined.--

"(i) Multiple source drug.--The term 'multiple source drug' means, with respect to a calendar quarter, a covered outpatient drug (not including any drug described in paragraph (5)) for which there are 2 or more drug products which--

"(I) are rated as therapeutically equivalent (under the Food and Drug Administration's most recent publication of 'Approved Drug Products with Therapeutic Equivalence Evaluations'),

"(II) except as provided in subparagraph (B), are pharmaceutically equivalent and bioequivalent, as defined in subparagraph (C) and as determined by the Food and Drug Administration, and

"(III) are sold or marketed in the State during the period.

"(ii) Innovator multiple source drug.--The term 'innovator multiple source drug' means a multiple source drug that was originally marketed under an original new drug application approved by the Food and Drug Administration.

"(iii) Noninnovator multiple source drug.--The term 'noninnovator multiple source drug' means a multiple source drug that is not an innovator multiple source drug.

"(iv) Single source drug.--The term 'single source drug' means a covered outpatient drug which is produced or distributed under an original new drug application approved by the Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributers operating under the new drug application.

"(B) Exception.--Subparagraph (A)(i)(II) shall not apply if the Food and Drug Administration changes by regulation the requirement that, for purposes of the publication described in subparagraph (A)(i)(I), in order for drug products to be rated as therapeutically equivalent, they must be pharmaceutically equivalent and bioequivalent, as defined in subparagraph (C).

"(C) Definitions.--For purposes of this paragraph--

"(i) drug products are pharmaceutically equivalent if the products contain identical amounts of the same active drug ingredient in the same dosage form and meet compendial

or other applicable standards of strength, quality, purity, and identity;

"(ii) drugs are bioequivalent if they do not present a known or potential bioequivalence problem, or, if they do present such a problem, they are shown to meet an appropriate standard of bioequivalence; and

"(iii) a drug product is considered to be sold or marketed in a State if it appears in a published national listing of average wholesale prices selected by the Secretary, provided that the listed product is generally available to the public through retail pharmacies in that State.

"(8) State agency.--The term 'State agency' means the agency designated under section 1902(a)(5) to administer or supervise the administration of the State plan for medical assistance.".

(b) Funding.--

<< 42 USCA § 1396b >>

(1) Drug use review programs.--Section 1903(a)(3) (42 U.S.C. 1936b(a)(3)) is amended--

(A) by striking "plus" at the end of subparagraph (C) and inserting "and", and

(B) by adding at the end the following new subparagraph:

"(D) 75 percent of so much of the sums expended by the State plan during a quarter in 1991, 1992, or 1993, as the Secretary determines is attributable to the statewide adoption of a drug use review program which conforms to the requirements of section 1927(g); plus".

<< 42 USCA § 1396b NOTE >>

(2) Temporary increase in federal match for administrative costs.--The per centum to be applied under section 1903(a)(7) of the Social Security Act for amounts expended during calendar quarters in fiscal year 1991 which are attributable to administrative activities necessary to carry out section 1927 (other than subsection (g)) of such Act shall be 75 percent, rather than 50 percent; after fiscal year 1991, the match shall revert back to 50 percent.

<< 42 USCA § 1396r-8 NOTE >>

(c) Demonstration Projects.--

(1) Prospective drug utilization review.--

(A) The Secretary of Health and Human Services shall provide, through competitive procurement by not later than January 1, 1992, for the establishment of at least 10 statewide demonstration projects to evaluate the efficiency and cost-effectiveness of prospective **drug** utilization review (as a component of on-line, real-time electronic point-of-sales claims management) in fulfilling patient counseling and in reducing costs for prescription **drugs**.

(B) Each of such projects shall establish a central electronic repository for capturing, storing, and updating prospective **drug** utilization review data and for

providing access to such data by participating pharmacists (and other authorized participants).

(C) Under each project, the pharmacist or other authorized participant shall assess the active **drug** regimens of recipients in terms of duplicate **drug** therapy, therapeutic overlap, allergy and cross-sensitivity reactions, **drug** interactions, age precautions, **drug** regiment compliance, prescribing **limits**, and other appropriate elements.

(D) Not later than January 1, 1994, the Secretary shall submit to Congress a report on the demonstration projects conducted under this paragraph.

(2) Demonstration project on cost-effectiveness of **reimbursement** for pharmacists' cognitive services.--

(A) The Secretary of Health and Human Services shall conduct a demonstration project to evaluate the impact on quality of care and cost-effectiveness of paying pharmacists under title XIX of the Social Security Act, whether or not a drug is dispensed, for drug use review services. For this purpose, the Secretary shall provide for no fewer than 5 demonstration sites in different States and the participation of a significant number of pharmacists.

(B) Not later than January 1, 1995, the Secretary shall submit a report to the Congress on the results of the demonstration project conducted under subparagraph (A).

(d) Studies.--

(1) Study of drug purchasing and billing activities of various health care systems.--

(A) The Comptroller General shall conduct a study of the drug purchasing and billing practices of hospitals, other institutional facilities, and managed care plans which provide covered outpatient drugs in the medicaid program. The study shall compare the ingredient costs of drugs for medicaid prescriptions to these facilities and plans and the charges billed to medical assistance programs by these facilities and plans compared to retail pharmacies.

(B) The study conducted under this subsection shall include an assessment of--

(i) the prices paid by these institutions for covered outpatient drugs compared to prices that would be paid under this section,

(ii) the quality of outpatient drug use review provided by these institutions as compared to drug use review required under this section, and

(iii) the efficiency of mechanisms used by these institutions for billing and receiving payment for covered outpatient drugs dispensed under this title.

(C) By not later than May 1, 1991, the Comptroller General shall report to the Secretary of Health and Human Services (hereafter in this section referred to as the "Secretary"), the Committee on Finance of the Senate, the Committee on Energy and Commerce of the House of Representatives, and the Committees on Aging of the Senate and the House of Representatives on the study conducted under subparagraph (A).

(2) Report on drug pricing.--By not later than May 1 of each year, the Comptroller General shall submit to the Secretary, the Committee on Finance of the Senate, the

Committee on Energy and Commerce of the House of Representatives, and the Committees on Aging of the Senate and House of Representatives an annual report on changes in prices charged by manufacturers for prescription drugs to the Department of Veterans Affairs, other Federal programs, retail and hospital pharmacies, and other purchasing groups and managed care plans.

(3) Study on prior approval procedures.--

(A) The Secretary, acting in consultation with the Comptroller General, shall study prior approval procedures utilized by State medical assistance programs conducted under title XIX of the Social Security Act, including--

(i) the appeals provisions under such programs; and

(ii) the effects of such procedures on beneficiary and provider access to medications covered under such programs.

(B) By not later than December 31, 1991, the Secretary and the Comptroller General shall report to the Committee on Finance of the Senate, the Committee on Energy and Commerce of the House of Representatives, and the Committees on Aging of the Senate and the House of Representatives on the results of the study conducted under subparagraph (A) and shall make recommendations with respect to which procedures are appropriate or inappropriate to be utilized by State plans for medical assistance.

(4) Study on reimbursement rates to pharmacists.--

(A) The Secretary shall conduct a study on (i) the adequacy of current reimbursement rates to pharmacists under each State medical assistance programs conducted under title XIX of the Social Security Act; and (ii) the extent to which reimbursement rates under such programs have an effect on beneficiary access to medications covered and pharmacy services under such programs.

(B) By not later than December 31, 1991, the Secretary shall report to the Committee on Finance of the Senate, the Committee on Energy and Commerce of the House of Representatives, and the Committees on Aging of the Senate and the House of Representatives on the results of the study conducted under subparagraph (A).

(5) Study of payments for vaccines.--The Secretary of Health and Human Services shall undertake a study of the relationship between State medical assistance plans and Federal and State acquisition and reimbursement policies for vaccines and the accessibility of vaccinations and immunization to children provided under this title. The Secretary shall report to the Congress on the Study not later than one year after the date of the enactment of this Act.

(6) Study on application of discounting of drugs under medicare.--The Comptroller General shall conduct a study examining methods to encourage providers of items and services under title XVIII of the Social Security Act to negotiate discounts with suppliers of prescription drugs to such providers. The Comptroller General shall submit to Congress a report on such study no later than 1 year after the date of enactment of this subsection.

EXHIBIT 103

Medicaid Prescription Reimbursement Information by State – Quarter Ending June 2009

ASP=average sale price, AWP=average wholesale price, WAC=wholesaler acquisition cost, NH=nursing home, FFS=fee for service SMAC=State maximum allowance cost and FUL=federal upper limit.
* Co-pay varies by cost of prescription.
** CMS Approved State Plans or State Source
Revised 07/09/2009

STATE	INGREDIENT COST	DISPENSING FEE	CO-PAYMENT	STATE MAC
State of Alabama	Ingredient cost is lower of WAC plus 9.2% or AWP minus 10%	Dispensing fee is $5.40	Co-payment is $0.50 to $3.00 *	STATE MAC Yes
State of Alaska	Ingredient cost is AWP minus 5%	Dispensing fee is $3.45 to $11.46 (based on pharmacy/Medicaid volume)	Co-payment is $2.00	STATE MAC No
State of Arizona	Ingredient cost is AWP minus 15%	Dispensing fee is $2.00 (FFS only)	No co-payment	STATE MAC No
State of Arkansas	Ingredient cost is AWP minus 20% (generic); AWP minus 14% (brand)	Dispensing fee is $5.51	Co-payment is $0.50 to $3.00 *	STATE MAC Yes
State of California	Ingredient cost is AWP minus 17%	Dispensing fee is $7.25; $8.00 (legend drugs dispensed to residents in skilled nursing facilities or intermediate care facilities)	Co-payment is $1.00	STATE MAC Yes
State of Colorado	Ingredient cost is lower of AWP minus 35% (generic); AWP minus 13.5% (brand) Direct Price plus 18%; AWP minus 12% (rural)	Dispensing fee is $4.00 (retail pharmacy); $1.89 (institutional pharmacy)	Co-payment is $1.00 (generic); $3.00 (brand)	STATE MAC Yes

STATE	INGREDIENT COST	DISPENSING FEE	CO-PAYMENT	STATE MAC
State of Connecticut	Ingredient cost is AWP minus 40% (selected multi-source brand and generic); AWP minus 14% (brand)	Dispensing fee is $3.15**	No co-payment	STATE MAC Yes
State of Delaware	Ingredient cost is AWP minus 14% (traditional, retail independent & retail chain pharmacies); AWP minus 16% (non-traditional, long term care & specialty pharmacies)	Dispensing fee is $3.65	No co-payment	STATE MAC Yes
District of Columbia	Ingredient cost is AWP minus 10%	Dispensing fee is $4.50	Co-payment is $1.00	STATE MAC No
State of Florida	Ingredient cost is lower of AWP minus 16.4% or WAC plus 4.75%	Dispensing fee is $4.23 (for non 340B billed drugs); $7.50 (340B billed drugs)	Co-payment for certain beneficiaries is 2.5% of payment up to $300, capped at 5% of total family income	STATE MAC YES
State of Georgia	Ingredient cost is AWP minus 11%	Dispensing fee is $4.63 (for profit pharmacy); $4.33 (not for profit)	Co-payment is $0.50 to $3.00	STATE MAC Yes
State of Hawaii	Ingredient cost is AWP minus 10.5%	Dispensing fee is $4.67	No co-payment	STATE MAC Yes
State of Idaho	Ingredient cost is AWP minus 12%	Dispensing fee is $4.94; $5.54 (unit dose)	No co-payment	STATE MAC Yes
State of Illinois	Ingredient cost is AWP minus 25% (generic); AWP minus 12% (brand)	Dispensing fee is $4.60 (generic); $3.40 (brand)	Co-payment is $3.00 (brand only)	STATE MAC Yes

STATE	INGREDIENT COST	DISPENSING FEE	CO-PAYMENT	STATE MAC
State of Indiana	Ingredient cost is AWP minus 16% (brand); AWP minus 20% (generic)	Dispensing fee is $4.90	Co-payment is $3.00	STATE MAC Yes
State of Iowa	Ingredient cost is AWP minus 12%	Dispensing fee is $4.57	Co-payment is $1.00 (non-preferred brand) (no more than $25.00), $2.00 (non-preferred brand) (between $25.01 and $50.00), $3.00 (non-preferred brand) ($50.01 or more)	STATE MAC Yes
State of Kansas	Ingredient cost is AWP minus 27% (generic); AWP minus 13% (brand)	Dispensing fee is $3.40	Co-payment is $3.00	STATE MAC Yes
State of Kentucky	Ingredient cost is AWP minus 14% (generic); AWP minus 15% (brand)	Dispensing fee is $5.00 (generic); $4.50 (brand)	Co-payment is $1.00 (generic or atypical anti-psychotic); $2.00 (brand without generic equivalent); $3.00 (non-preferred brand); cap $225 per year per recipient	STATE MAC Yes
State of Louisiana	Ingredient cost is AWP minus 13.5% (independent pharmacies); (AWP minus 15% (chain pharmacies)	Dispensing fee is $5.77**	Co-payment is $0.50 to $3.00 *	STATE MAC Yes

STATE	INGREDIENT COST	DISPENSING FEE	CO-PAYMENT	STATE MAC
State of Maine	Ingredient cost is AWP minus 15%; AWP minus 17% (on direct supply); AWP minus 20% (mail order)	Dispensing fee is $3.35; $1.00 (mail order); $4.35 and $5.35 (compounding); $12.50 (insulin syringe)	Co-payment is $3.00 (not to exceed $30 per month) No co-payments for mail order	STATE MAC Yes
State of Maryland	Ingredient cost is lower of AWP minus 12%, WAC plus 8%, direct price plus 8% or distributor price when available	Dispensing fee is $3.69 (generic); $2.69 (brand); $4.69 (generic to NH); $3.69 (brand to NH); $7.25 (home IV therapy)	Co-payment is $1.00 (generic and preferred brand); $3.00 (non-preferred brand)	STATE MAC Yes
State of Massachusetts	Ingredient cost is WAC plus 5% (all drugs except 340B billed drugs); actual acquisition cost (340B billed drugs)	Dispensing fee is $3.00 (all drugs except 340B billed drugs); $10 (340B billed drugs)	Co payment is $1.00 (multiple source and OTC); $3.00 (all other drugs)	STATE MAC Yes
State of Michigan	Ingredient cost is AWP minus 13.5% (independent pharmacy (1 to 4 stores); AWP minus 15.1% (chain pharmacies (5+ stores)	Dispensing fee is $2.50; $2.75 (long term care)	Co-payment is $1.00 (generic); $3.00 (brand)	STATE MAC Yes
State of Minnesota	Ingredient cost is AWP minus 12%	Dispensing fee is $3.65 (+$0.30 for legend unit dose drugs)	Co-payment is $1.00 (generic); $3.00 (brand)	STATE MAC Yes
State of Mississippi	Ingredient cost is lower of AWP minus 12% or WAC plus 9% (brand); AWP minus 25% (generic)	Dispensing fee is $3.91 (brand); $5.50 (generic)	Co-payment is $3.00 (medically needy only)	STATE MAC Yes
State of Missouri	Ingredient cost is lower of AWP minus 10.43% or WAC plus 10%	Dispensing fee is $4.09	Co-payment is $0.50 to $2.00 *	STATE MAC Yes

STATE	INGREDIENT COST	DISPENSING FEE	CO-PAYMENT	STATE MAC
State of Montana	Ingredient cost is AWP minus 15%	Dispensing fee is $4.94; $12.50 to $22.50 (compounding)	Co-payment is $1.00	STATE MAC No
State of Nebraska	Ingredient cost is AWP minus 11%	Dispensing fee is $3.27 to $5.00 (based on service delivery, unit dosage or 3rd party payors)**	Co-payment is $2.00	STATE MAC Yes
State of Nevada	Ingredient cost is AWP minus 15%	Dispensing fee is $4.76; $22.40 daily (home IV therapy); $16.80 daily (nursing facility IV therapy)	No co-payment	STATE MAC No
State of New Hampshire	Ingredient cost is AWP minus 16%	Dispensing fee is $1.75	Co-payment is $1.00 (generic); $2.00 (brand & compound)	STATE MAC Yes
State of New Jersey	Ingredient cost is AWP minus 15%	Dispensing fee is $3.73 up to $3.99 (twenty-four hour emergency service and impact area location)**	No co-payment	STATE MAC Yes
State of New Mexico	Ingredient cost is lower of AWP minus 14%; wholesaler average cost as submitted to State; manufacturer price as submitted to State; pharmacy invoice price as obtained through audits.	Dispensing fee is $3.65	No co-payment **	STATE MAC Yes
State of New York	Ingredient cost is AWP minus 16.25% (brand); AWP minus 25% (generic); AWP minus 12% (specialized HIV pharmacies)	Dispensing fee is $4.50 (generic); $3.50 (brand)	Co-payment is $1.00 (generic); $3.00 (brand); $.50 (OTC)	STATE MAC Yes
State of North	Ingredient cost is AWP minus 10%, ASP	Dispensing fee is $5.60 (generic);	Co-payment is $1.00	STATE

STATE	INGREDIENT COST	DISPENSING FEE	CO-PAYMENT	STATE MAC
Carolina	plus 6.7% (physician administered drugs)	$4.00 (brand)	(generic); $3.00 (brand)	MAC Yes
State of North Dakota	Ingredient cost is lower of AWP minus 10% or WAC plus 12.5%	Dispensing fee is $5.60 (generic); $4.60 (brand); plus $0.15 per pill (pill splitting)	Co-payment is $3.00 (brand)	STATE MAC Yes
State of Ohio	Ingredient cost is WAC plus 7% or if WAC cannot be determined, ingredient cost is AWP minus 14.4%	Dispensing fee is $3.70	Co-payment is $3.00 (non preferred drugs); $2.00 (preferred brand drugs)	STATE MAC Yes
State of Oklahoma	Ingredient cost is AWP minus 12%	Dispensing fee is $4.15	Co payment is $1.00 to $2.00 *	STATE MAC Yes
State of Oregon	Ingredient cost for multiple source drugs is AWP minus 15%; AWP minus 11% (institutional); AWP minus 68% (mail order); Ingredient cost for single source drugs is AWP minus 15%; AWP minus 11% (institutional); AWP minus 21% (mail order)	Dispensing fee is $3.50 (retail); $3.91 (institutional)	Co-payment is $1.00 (non preferred generic or generics costing $10.00); No co-payment (preferred generic & brand); $3.00 (all other brands)	STATE MAC Yes
State of Pennsylvania	Ingredient cost is lower of WAC plus 7% or AWP minus 14%	Dispensing fee is $4.00; $5.00 (compounding)	Co-payment is $1.00	STATE MAC Yes
State of Rhode	Ingredient cost is WAC	Dispensing fee is $3.40	No co-payment	STATE

STATE	INGREDIENT COST	DISPENSING FEE	CO-PAYMENT	STATE MAC
Island		(outpatient), $2.85 (long term care)		MAC No
State of South Carolina	Ingredient cost is AWP minus 10%	Dispensing fee is $4.05 (independent pharmacy); $3.15 (institutional pharmacies)	Co-payment is $3.00	STATE MAC Yes
State of South Dakota	Ingredient cost is AWP minus 10.5%	Dispensing fee is $4.75; $5.55 (unit dose)	Co-payment is $3.00 (brand)	STATE MAC Yes
State of Tennessee	Ingredient cost is lower of AWP minus 16%, MAC or FUL for Pharmacy Benefit Management (PBM) National Network. Ingredient cost is lower of AWP minus 13%, MAC or FUL for TennCare Pharmacy Network. Special Pharmacy Rates are set separately	Dispensing fee for Pharmacy Benefit Management (PBM) National is $1.50 Dispensing fee for TennCare Pharmacy Network is $2.50 (brand); $3.00 (generic); $5.00 (brand nursing home) $6.00 (generic nursing home); $25 (compound prescriptions)	$0 (generics) and (Categorically Needy) $3.00 (Medically Needy)	STATE MAC Yes
State of Texas	Ingredient cost is lower of AWP minus 15% or WAC plus12%	Dispensing fee is $5.14 plus 1.95% of cost of drug	No co-payment **	STATE MAC Yes
State of Utah	Ingredient cost is AWP minus 15%	Dispensing fee is $3.90 (urban); $4.40 (rural)**	Co-payment is $3.00 **	STATE MAC Yes
State of Vermont	Ingredient cost is AWP minus 11.9%	Dispensing fee $4.75 (In-State) $3.65 (Out-of-State)	Co-payment is $1.00 to $3.00 *	STATE MAC Yes
State of	Ingredient cost is AWP minus 10.25%	Dispensing fee is $4.00; $5.00	Co-payment is $1.00	STATE

STATE	INGREDIENT COST	DISPENSING FEE	CO-PAYMENT	STATE MAC
Virginia		(unit dose drugs)		MAC Yes
State of Washington	Ingredient cost is AWP minus 14% (single source drugs); AWP minus 14% (multi-source drugs with four or fewer manufacturers/labelers); AWP minus 50% (multi-source drugs with five or more manufacturers/labelers and no MAC or FUL	Dispensing fee is $4.20 to $5.20 (based on 3-tiered pharmacy volume)	No co-payment	STATE MAC Yes
State of West Virginia	Ingredient cost is AWP minus 15% (brand); AWP minus 30% (generic)	Dispensing fee is $2.50 (brand); $5.30 (generic); $8.25 (340B billed drugs)	Co-payment is $0.50 to $3.00 *	STATE MAC Yes
State of Wisconsin	Ingredient cost is AWP minus 13%	Dispensing fee is $4.38; $0.015 per unit (for repackaging); $9.45 to $22.16 (compound drug fee); $9.45 to $40.11 (pharmaceutical care dispensing fee)	Co-payment is $0.50 (over-the-counter); $3.00 (brand); $1.00 (generic); cap $12 per pharmacy per recipient per month	STATE MAC Yes
State of Wyoming	Ingredient cost is AWP minus 11%	Dispensing fee is $5.00	Co-payment is $2.00	STATE MAC Yes